A collaborative and agile pharmaceutical company with an R&D focus on infectious diseases and a leading position in hepatitis C

Q1-2013 Conference Call - Presenting team

Maris Hartmanis, CEO
Charlotte Edenius, EVP Development
Rein Piir, EVP Corporate Affairs & IR

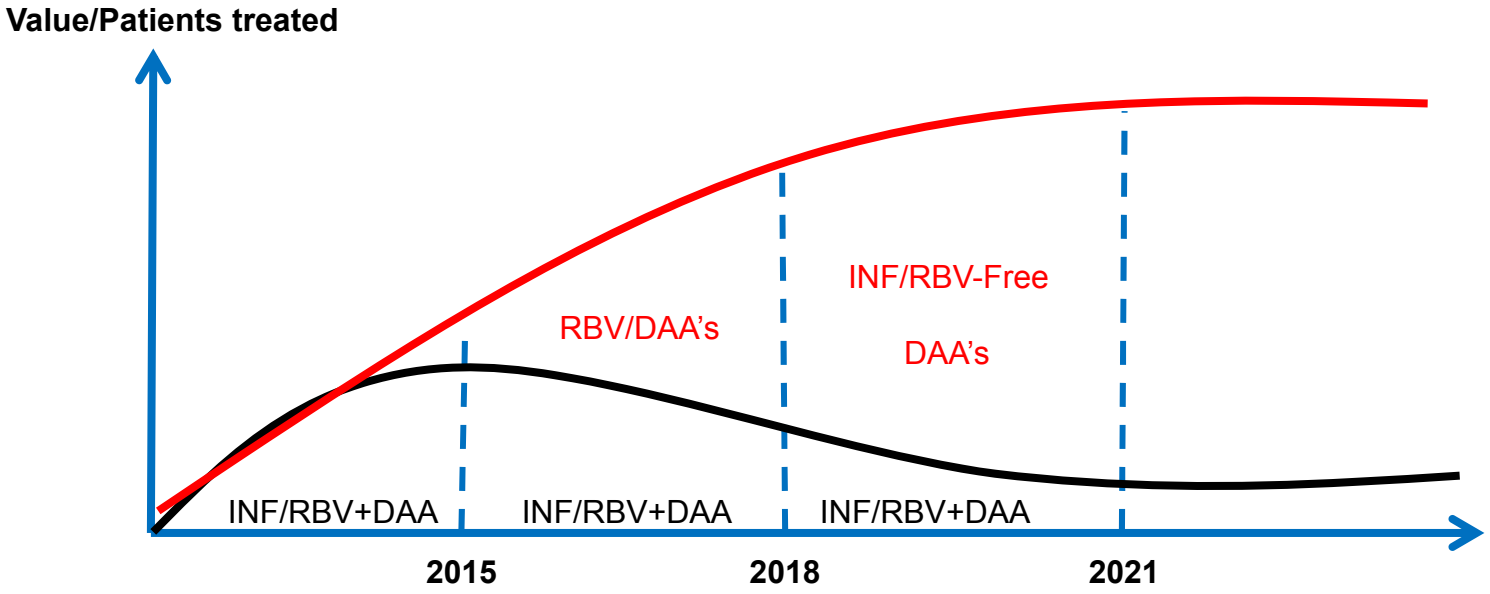
Reflections on Q1 2013

Maris Hartmanis, CEO

Long term goal – eradication of hepatitis C

The evolution in treating hepatitis C will expand the market value, number of patients treated and regions over the next 10-15 years

Regional, patient and pricing differences will drive the segments in the future



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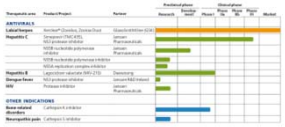
Value proposition – a platform for growth and profitability



Innovative portfolio that will evolve over time

- World class expertise in polymerase and protease drug targets
- R&D focus on infectious diseases

Strong position in HCV area

- Simeprevir, partnered with Janssen Pharmaceuticals
  - Regulatory files submitted in EU, US and Japan
  - Many interferon-free combination treatment opportunities
- In-house HCV programs will offer new combination opportunities

Commercial presence in the Nordic region creates stability

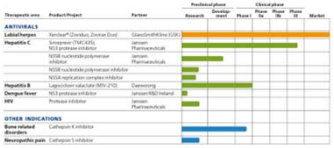
- Solid brand names with annual sales of ~85 MUSD
- Commercial platform for the launch of simeprevir in the Nordics in 2014
- Pharmaceutical portfolio will be broadened

BioPhausia® – a Medivir sales company

Solid financial position

- Present assets are solid and will take us to profitability

2013 - Setting the framework for becoming
The Emerging European Pharma Company



Structure

- Broader, risk balanced R&D pipeline
- Continued commitment towards targets in infectious diseases
- Addressing new therapeutic areas based on core competence
- Partner of choice for both pharmaceuticals and development programs
- Expansion of product portfolio, including simeprevir and other in-house developed pharmaceuticals

External perspective

- Top ranked as a listed company
- Profitable and fast growing Nordic based pharmaceutical company

Important events in Q1, 2013

Overall operations

- Continued growth of Medivir's pharmaceutical business
- € 15m in milestone payments strengthened financial position further
- Strengthening of R&D leadership

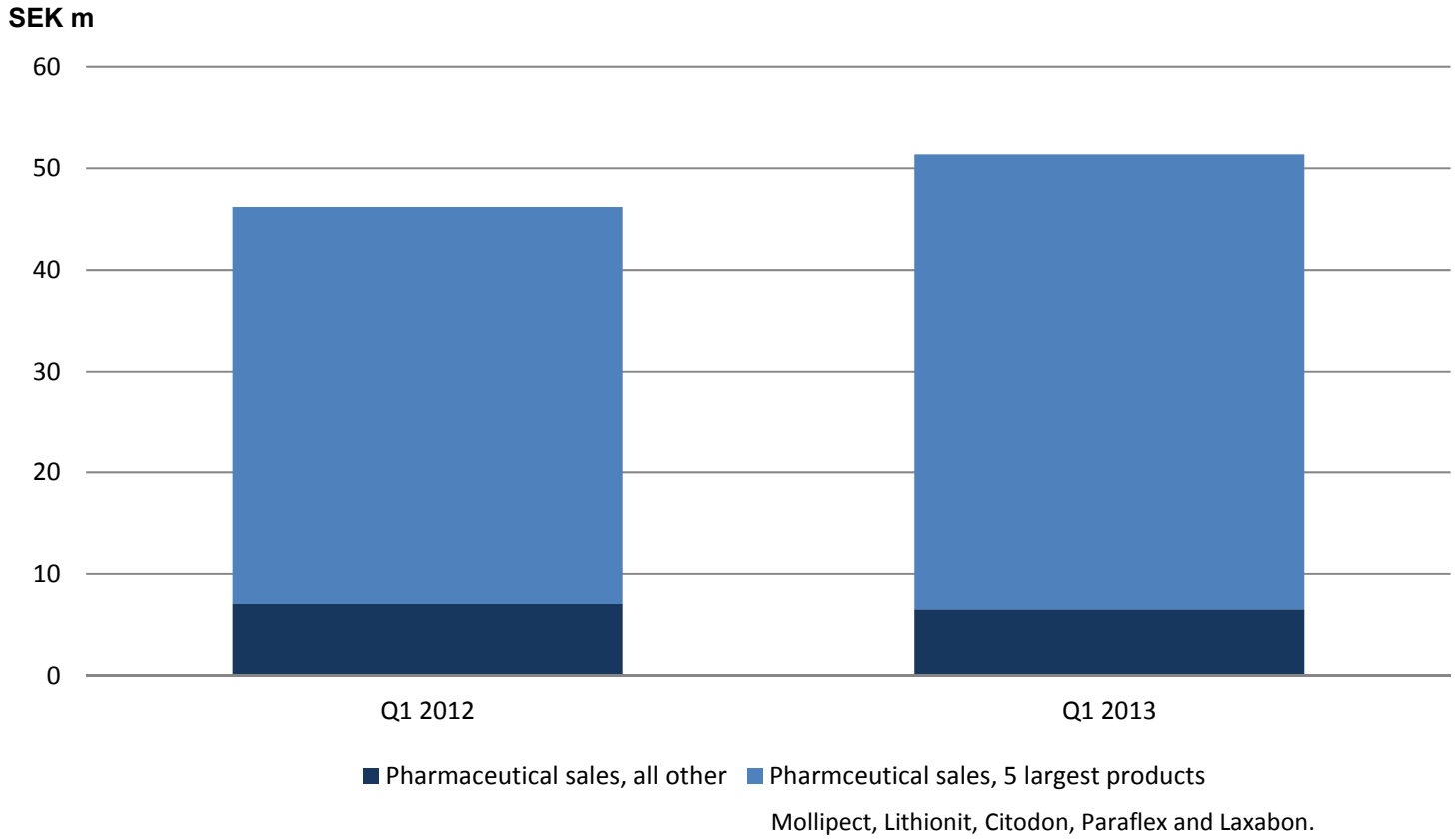
Simeprevir

- Filing in three major regions in two months, launch anticipated in late 2013
- Clinical collaboration agreement with IDENIX on interferon free regimens, trials underway
- All five interferon free combination trials with simeprevir making progress, data expected during 2013
- First interferon- and ribavirin-free data from combination of simeprevir and sofosbovir presented, showing the great potential of combining a PI with a Nuke in hard to treat patients.

R&D

- Cathepsin K and S projects moving towards important value inflection points
- Internal HCV projects moving forward
- The joint venture project with Janssen on dengue was closed

Segment Pharmaceutical, sales Q1 2012 vs. Q1 2013



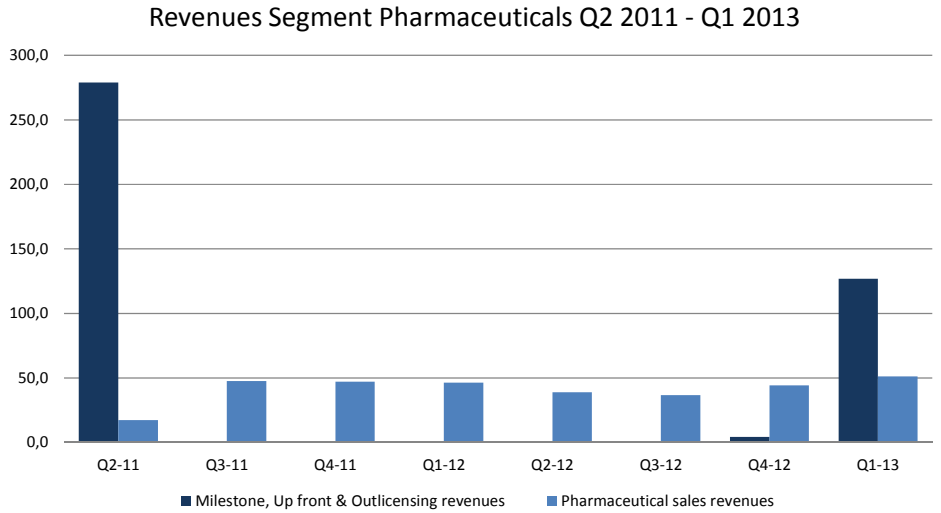
Consolidated profit performance

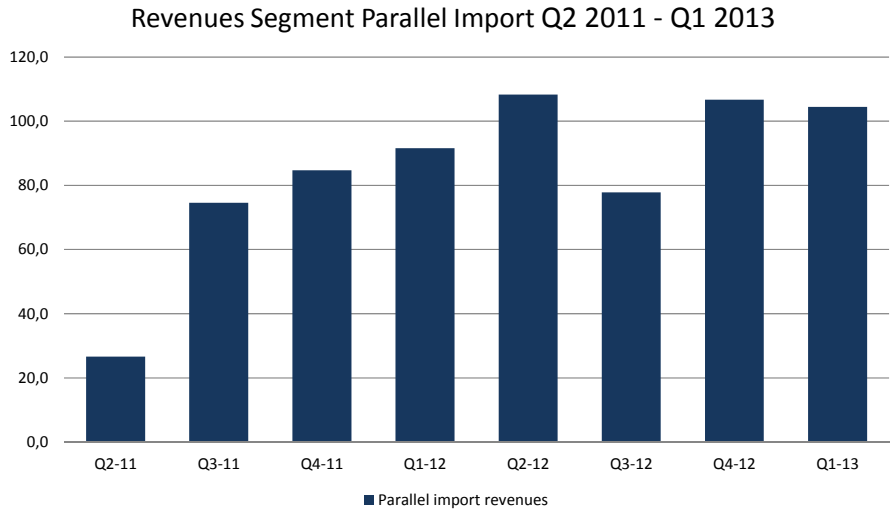
(SEK m)	2013 Jan-Mar	2012 Jan-Mar	2012 Jan-Dec
Net turnover	282.6	137.9	555.0
Gross profit	171.3	40.9	152.3
EBITDA	84.7	-29.9	-151.0
EBIT	83.0	-38.3	-185.8
Profit/loss before tax	83.0	-37.5	-192.9
Profit/loss after tax	77.6	-37.7	-219.1

Net turnover breakdown

(SEK m)	2013 Jan-Mar	2012 Jan-Mar	2012 Jan-Dec
Outlicensing and partnership agreements/Non-recurrent payments	126.8	-	4.4
Pharmaceutical sales	51.3	46.3	164.9
Parallel imports	104.5	91.6	384.4
Other services	0.0	0.0	1.3
Total	**282.6**	**137.9**	**555.0**

Quarterly sales trend in Pharmaceuticals and Parallel imports, SEK m*





*The BioPhausia corporate group is included from 31 May 2011.

Key R&D highlights from Q1 2013

Charlotte Edenius, EVP Development

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Pipeline status end Q1 2013

Therapeutic area	Product/Project	Partner
ANTIVIRALS		
Labial herpes	Xerclear® (Zoviduo, Zovirax Duo)	GlaxoSmithKline (GSK)
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals
Hepatitis B	Lagociclovir valactate (MIV-210)	Daewoong
Hepatitis C	NS5B nucleotide polymerase inhibitor	Janssen Pharmaceuticals
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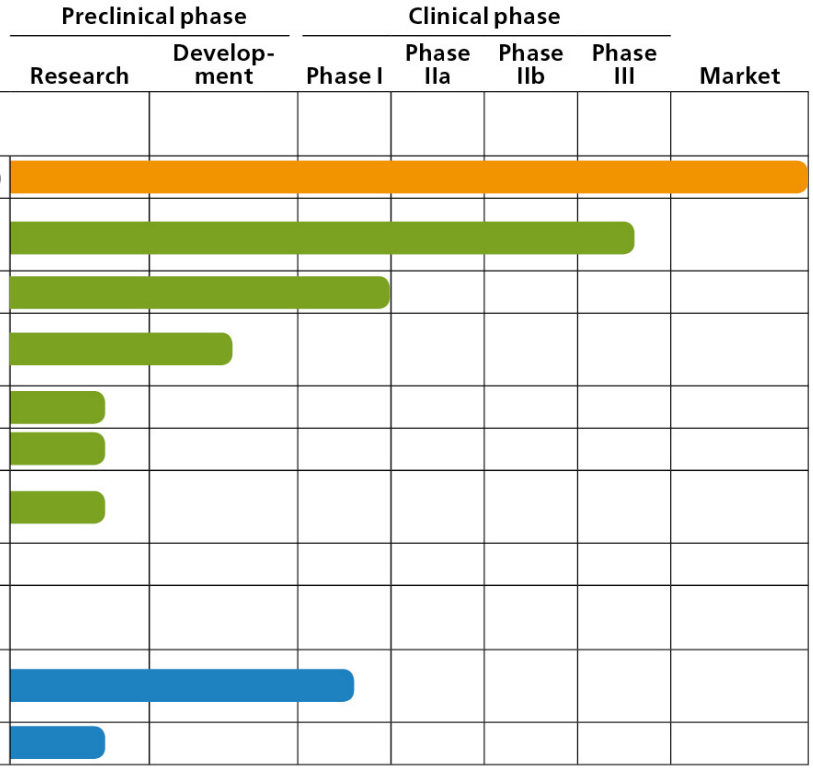
Hepatitis C	NS5A replication complex inhibitor	
HIV	Protease inhibitor	Janssen Pharmaceuticals
OTHER INDICATIONS		
Bone related disorders	Cathepsin K inhibitor	
Neuropathic pain	Cathepsin S inhibitor	



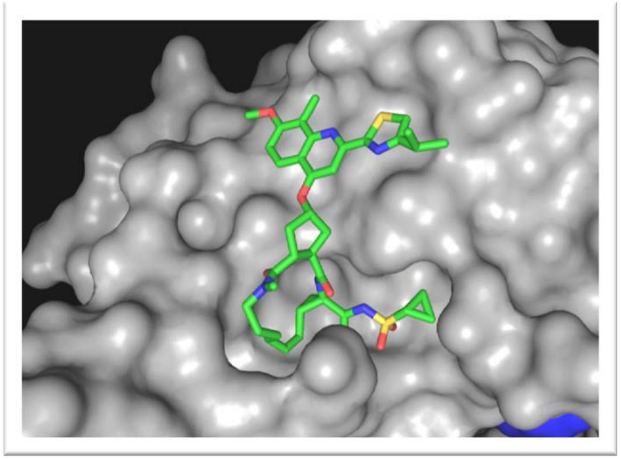
Pipeline status end Q1 2013

- **Cathepsin K inhibitor program** (bone related disorders):
  - Experimental part in clinical phase Ib study successfully finalised
  - Single ascending dose data to be presented at the European Calcified Tissue Society (ECTS) annual meeting in Lisbon 18-21/5
  - All data available June 2013 (safety, PK and biomarker)

- **Cathepsin S program** (neuropathic pain)
  - Continues according to plan; currently profiling best compounds, aiming for a candidate selection H1-2013

- **Internal HCV programs**
  - Both nucleotide and NS5A inhibitor programs targeting CD selection in H2 2013

Simeprevir – a new generation NS3/4 protease inhibitor



Administered as **one capsule once daily** with pegylated interferon and ribavirin for the treatment of **genotype 1 or genotype 4** chronic hepatitis C in adult patients with compensated liver disease (**including cirrhosis**), with or without **HIV-1 co-infection**, who are **treatment naive or who have failed previous interferon therapy**

- Antiviral activity against HCV GT 1, 2, 4, 5, and 6
- Three large pivotal phase III studies of SMV 150 mg QD plus PegIFN/RBV completed
- Safe and well tolerated with high SVR rates
- Simeprevir is currently being studied in a number of IFN-free regimens, including the COSMOS study

Simeprevir - clinical development programs in HCV G1 & 4 infected patients

Pivotal phase III studies:

- **QUEST 1** treatment-naïve
- **QUEST 2** treatment-naïve
- **PROMISE** prior relapsers
- **Japan** naïve & experienced (four studies)

Regulatory files submitted in US (March-13) and in EU (April-13)

Regulatory file submitted in Japan Feb-13

Other ongoing phase III studies:

- **China:** Efficacy, PK, safety and tolerability in naïve patients
- **ATTAIN:** Simeprevir vs telaprevir in prior null or partial responders
- **RESTORE: HCV genotype 4 infected** naïve or treatment experienced patients
- **C212: HIV-HCV** co-infected treatment naïve and treatment experienced patients

Regulatory filings for simeprevir triple combination submitted in US, EU & Japan

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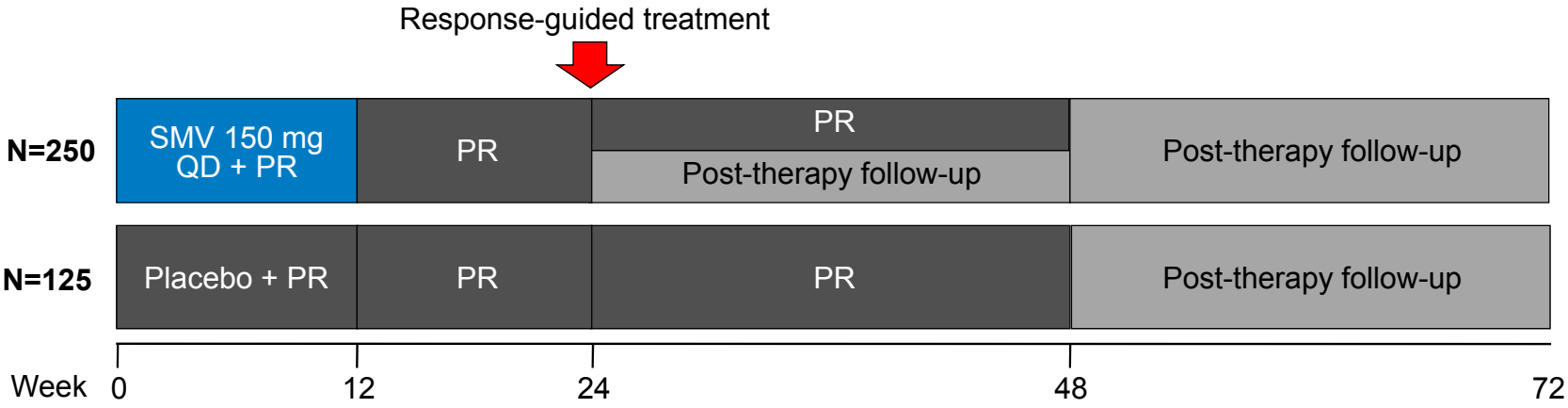
For additional information, please see www.clinicaltrials.gov

Simeprevir - Phase III Study designs in HCV GT1 infected patients (QUEST-1, QUEST-2 and PROMISE)

- Randomized, double-blind, placebo controlled design
- Patients were stratified by HCV subtype and IL28B genotype



PR: PegInterferon + Ribavirin

Studies:

QUEST-1: n=394, naive (METAVIR score F3-F4: 30%)

QUEST-2: n=391, naive, (METAVIR score F3-F4: 22%)

PROMISE: n=393, prior relapsers, (METAVIR score F3-F4: 31%)

Top line data Dec-12

Reported at EASL 2013

SVR12 data from QUEST-1 and QUEST-2

Patients with SVR12 %	QUEST-1		QUEST-2	
	SMV + PR	Placebo + PR	SMV + PR	Placebo + PR
All patients	**80**	50	**81**	50
SVR12 with 24 wks treatment (% pat meeting RGT criteria)	**91 (85)**	N/A	**86 (91)**	N/A
CC / CT / TT	**94 / 76 / 65**	78 / 42 / 24	**96 / 80 / 58**	81 / 41 / 19
GT1a & other / GT1b	**71 / 90**	49 / 52	**80 / 82**	46 / 53
F0-F2	**83**	60	**85**	51
F3-F4	**70**	28	**66**	47

Robust data from two large placebo-controlled studies including a large proportion of patients with advanced liver fibrosis (F3-F4)

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Most common adverse events in QUEST-1 and QUEST-2 during the first 12 weeks of treatment

Patients, %	QUEST-1		QUEST-2	
	SMV/PR (N=257)	PBO/PR (N=134)	SMV/PR (N=257)	PBO/PR (N=134)
Most common AEs (≥25% in SMV arm)				
Fatigue	40	38	35	39
Pruritus	21	11	19	15
Headache	31	37	37	34
Pyrexia			30	36
Influenza-like illness			26	26
AEs of interest				
Rash (any type)	27	25	24	11
Anemia	16	11	14	16

Overall incidence of adverse events was similar to placebo control

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Simeprevir - Phase III summary and regulatory status

79-81% overall SVR12 rates[1]:

- Naive and relapser patients in three large global studies (QUEST-1 & -2, and PROMISE)
- *SVR12 rates confirmed in Japan program*[2]

86-91% SVR12 rates with 24 weeks treatment in QUEST-1 and -2

- 85-91% of patients stopped all treatment at 24 weeks

Excellent safety and tolerability

- Overall incidence of adverse events similar to placebo, including rash and anemia
- *Safety and tolerability confirmed in Japanese studies*[2]

Regulatory applications filed for approval of simeprevir in:

- **Japan** for hepatitis C genotype 1, treatment naïve, prior non-responders or relapsed
- **US** for hepatitis C genotype 1
- **EU** for hepatitis C genotype 1 or 4

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[1] All three trials included hard-to-cure patients with advanced liver fibrosis/cirrhosis (METAVIR score F3-F4)
[2] To be presented at upcoming scientific meetings

Simeprevir - clinical development programs in HCV G1 & 4 infected patients

Pivotal phase III studies:

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- **C212: HIV-HCV** co-infected treatment naïve and treatment experienced patients

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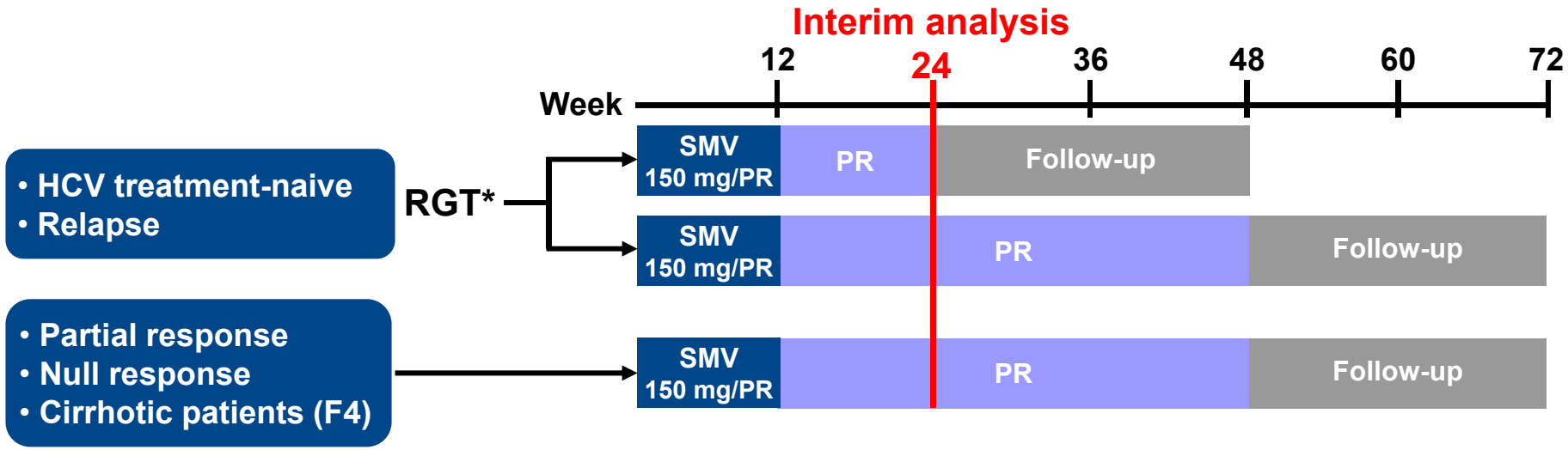
C212 HCV-HIV Co-infected

Study design



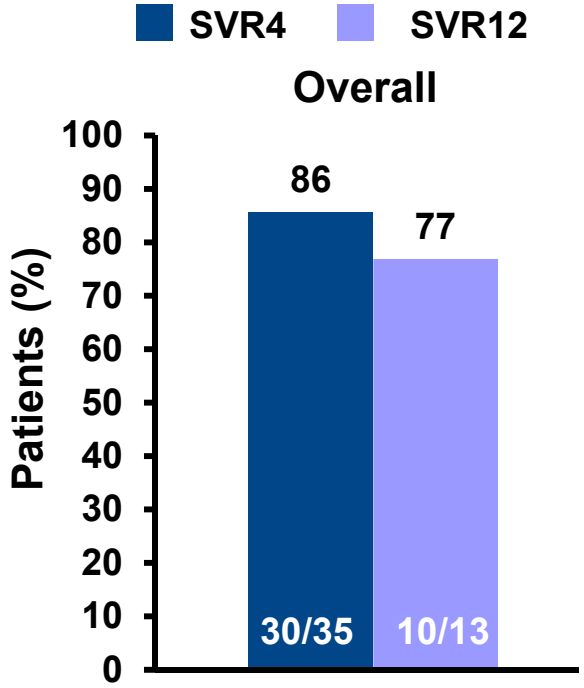
Interim analysis:

- **All patients included in the analysis had completed 24 weeks of treatment or had discontinued prior to that point**

- **No. of patients:** **Week 24: N=100**
  Week 28: N=71
  Week 36: N=27

C212: HCV-HIV Co-infected

Preliminary SVR4 and SVR12 rates in patients treated with SMV/PR



- 82% GT1a,
- 21% (METAVIR F3/4)
- 93 out of 106 patients on ARV therapy
- 88% met RGT criteria and stopped all treatment at W24
- Simeprevir was safe and well tolerated
- No HIV breakthroughs

In the US 25 % of HIV patients are coinfected with HCV

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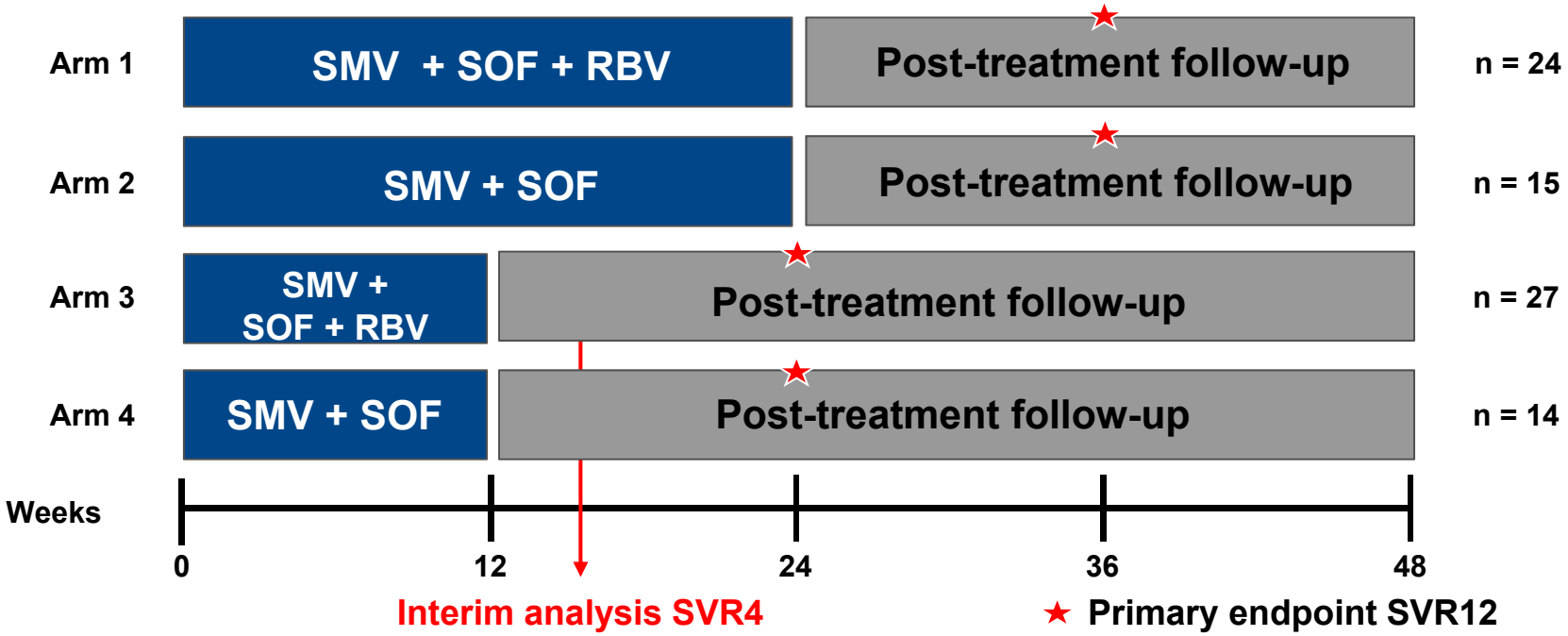
The full presentation is available at the CROI web site

Simeprevir

- All oral interferon free combination update

COSMOS - Once-daily regimen of simeprevir plus sofosbuvir with or without ribavirin in HCV genotype 1 null responders*



- Cohort 1: n=80, nulls, F0-F2
- Cohort 2: n=87, naives and nulls, F3-F4
- SMV 150 mg QD + SOF 400 mg QD
- Interim analysis of Cohort 1 conducted when all patients in 12 week treatment arms reached SVR4 time point or discontinued early

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*The **COSMOS** study: **CO**mbination of **SiM**eprevir and s**O**fosbuvir in HCV infected patie**ntS**

COSMOS study - Baseline patient demographics and HCV disease characteristics

Patients		Total (n=80)
Patient demographics		
Male		61%
Race	Caucasian	71%
	African American	29%
Ethnicity	Hispanic/Latino	25%
Age, years, median		56.0
BMI, kg/m^2, median		27.5
IL28B	nonCC	94%
Baseline characteristics		
HCV subtype 1a		78%
HCV RNA, median, log_{10} IU/mL		6.8
METAVIR score	F0-F1	41%
	F2	59%

COSMOS study – Efficacy results (interim analysis)

Response rates	12 weeks treatment	
	SMV + SOF+ RBV (n=27)	SMV + SOF (n=14)
RVR[1], n/N (%)	23/27 (85)	8/14 (57)
Undetectable end of treatment, n/N (%)	27/27 (100)	14/14 (100)
Relapse, n	1	1
SVR4, n/N (%)	**26/27 (96)**	**13/14 (93)**
SVR8, n/N (%)	**26/27 (96)**	**13/14 (93)**

Of the patients in the **12 week arms** who achieved SVR8

– **24/24** who reached post-treatment Week 12 had achieved **SVR12**

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[1]RVR is based on patients with available data at Week 4 (2 patients discontinued before Week 4)
EOT, end of treatment; RVR, rapid virologic response; SMV, simeprevir;
SOF, sofosbuvir; SVR, sustained virologic response

The full presentation is available at the CROI web site

COSMOS study - Summary & Conclusions

- SMV + SOF with or without RBV for 12 weeks yielded high SVR rates in prior null responders with mild to moderate fibrosis (METAVIR F0-F2)
  - ✓ **SVR8 rate of 96% with RBV and 93% without RBV**

- SMV + SOF was safe and well tolerated
  - ✓ Anemia was seen only in RBV arms
  - ✓ Bilirubin increases only occurred in RBV containing arms

Enrollment of Cohort 2 is complete and include prior null responders and treatment-naïve patients all with advanced fibrosis (METAVIR F3-F4)

Simeprevir in interferon-free combinations

			Ribavirin			
Simeprevir	**+**	**Sofosbuvir** (nucleotide)	**+/-**	12w	N=80+87 ✓Cohort a: nulls, F0-F2 Cohort b: nulls + naives; **F3/4 (cirrhotics)**
			+/-	24w	
Simeprevir	**+**	**Daclatasvir** (NS5A inhibitor)	**+/-**	12w	N=180 Naives and nulls **Incl. F3/4 up to 35 %**
			+/-	24w	
Simeprevir	**+**	**TMC647055/r** (NNI; non-nucleoside)	**+/-**	12w	Naives/relapser and nulls Non-cirrhotics
Simeprevir	**+**	**VX-135** (nucleotide)	**+/-**	12w	DDI studie ongoing Phase II to start H2 2013
Simeprevir	**+**	**IDX719** (NS5A inhibitor) **+/- TMC647055/r**	**+/-**	12w	Phase II to start Q2

Simeprevir is strongly positioned to become a principal component of future IFN-free therapies

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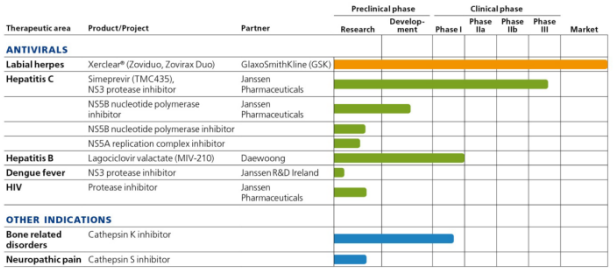
For additional information, please see www.clinicaltrials.gov

News flow - highlights



Therapeutic area	Product/Project	Partner	Preclinical phase: Research	Preclinical phase: Develop-ment	Clinical phase: Phase I	Clinical phase: Phase IIa	Clinical phase: Phase IIb	Clinical phase: Phase III	Market
ANTIVIRALS									
Labial herpes	Xerclear® (Zoviduo, Zovirax Duo)	GlaxoSmithKline (GSK)							
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals							
	NS5B nucleotide polymerase inhibitor	Janssen Pharmaceuticals							
	NS5B nucleotide polymerase inhibitor								
	NS5A replication complex inhibitor								
Hepatitis B	Lagociclovir valactate (MIV-210)	Daewoong							
Dengue fever	NS3 protease inhibitor	Janssen R&D Ireland							
HIV	Protease inhibitor	Janssen Pharmaceuticals							
OTHER INDICATIONS									
Bone related disorders	Cathepsin K inhibitor								
Neuropathic pain	Cathepsin S inhibitor								

- ✓ Q4-12 Start of Cohort 2 with simeprevir and GS7977 phase II study
- ✓ Q4-12 Top line results from phase III trials with simeprevir (Quest 1+2 and Promise)
- ✓ Q1-13 Filing for regulatory approval in Japan
- ✓ H1-13 EoT and partial SVR data from Cohort 1 with simeprevir and sofosbuvir phase II study
- ✓ H1-13 Filing of simeprevir in Japan, the US and EU
- H1-13 Potential CD selection in Cathepsin S (neuropathic pain) program
- H1-13 Results from phase I-study with MIV-711, our cathepsin K inhibitor (bone related disorders)
- H1-13 Step two in GSK launch strategy for Xerclear® (ZoviDuo), launch in major European OTC markets
- H2-13 Start of Phase II with simeprevir and VX-135
- H2-13 Potential CD selection in our internal Nucleotide NS5B inhibitor program
- H2-13 Potential CD selection in our internal NS5A inhibitor program
- H2-13 Goal to start phase I trials with Medivir/Janssen nucleotide NS5B-inhibitor
- H2-13 Data from the phase II combination study with simeprevir and daclatasvir
- H2-13 SVR data from Cohort 2 with simeprevir and sofosbuvir phase II study

www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

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